REMARKS

This Amendment is submitted in response to the Office Action mailed on February 27, 2001. In the Office Action, Claims 1-9 are rejected under 35 U.S.C. § 112, 2nd paragraph; Claim 3 is rejected under 35 U.S.C. § 112, 1st paragraph; Claims 1-10 are rejected under 35 U.S.C. § 102(b); and Claims 1-10 are rejected under 35 U.S.C. § 103(a). Claims 1-10 have been cancelled; and Claims 11-23 have been newly added. Applicants respectfully submit that the rejections of the pending claims have been overcome or are improper in view of the amendments and for the reasons set forth below.

At the outset, the Patent Office asserts that a new oath or declaration is required in the body of which the present application should be identified by application number and filing date. In response, Applicants have submitted a new oath or declaration attached herewith in compliance with the requirements of 37 C.F.R. 1.63.

In the Office Action, Claims 1-9 are rejected under 35 U.S.C. § 112, 2nd paragraph as being indefinite. The Patent Office assets that Claims 1-9 provide for the use of *lactobacteria*, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process Applicants are intending to encompass. With respect to Claim 4, the Patent Office asserts that this claim is indefinite because it fails to point out amounts of *lactobacteria*. Further, the Patent Office asserts that Claims 1-9 are indefinite with respect to the term "*lactobacilli*."

As previously discussed, Claims 1-10 have been cancelled and therefore the rejection of Claims 1-9 under 35 U.S.C. § 112 has been rendered moot. Further, Claims 11-23 have been newly added. Applicants submit that the newly added claims fully comply with 35 U.S.C. § 112.

With respect to the Patent Office's comments with respect to the term "*lactobacilli*", Applicants submit that *lactobacilli* is the correct term for the plural of *Lactobacillus*. In this regard,

the term *lactobacilli* is meant to include any number or combination of different *Lactobacillus* strains as fully supported in the Specification at page 3 on lines 9-19. Therefore, Applicants question why the Patent Office asserts that the use of this term is unclear.

Accordingly, Applicants respectfully request that the rejection of the pending claims under 35 U.S.C. § 112, 2nd paragraph be withdrawn.

In the Office Action, Claim 3 is rejected under 35 U.S.C. § 112, 1st paragraph. The Patent Office asserts that the Specification does not disclose a repeatable process to obtain the microorganism and it is not clear from the Specification record that the microorganism is readily available to the public.

In response, Applicants submit that a deposit has been made in accordance with the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent. Further, Applicants have submitted a statement from the Collection Nationale de Culture de Microorganismes (attached herewith) evidencing the deposit of same.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, 1st paragraph be withdrawn.

In the Office Action, Claims 1-10 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,494,664 ("*'664*") or by U.S. Patent No. 5,578,302 ("*'302*"). The Patent Office asserts that each reference discloses each and every feature of the claimed invention.

Applicants submit that this rejection is improper. At the outset, Claims 1-10 have been cancelled and therefore this rejection has been rendered moot with respect to Claims 1-10. As previously discussed, Claims 11-23 have been newly added.

Of the newly added claims, Claims 11, 19 and 23 are independent claims. Claim 11 recites a method for the treatment or prophylaxis of mineral deficiencies in a mammal comprising the steps of enterally administering to the mammal a nutritional composition comprising *lactobacilli*. Claim 19 recites a method for increasing absorption of minerals from a diet comprising the steps of enterally administering to a mammal a nutritional composition comprising *lactobacilli*. Claim 23 recites a method for improving the absorption of minerals in a mammal comprising the steps of enterally administering to the mammal a nutritional composition comprising *lactobacilli*.

Applicants have surprisingly found, by use of an *in vitro* model, that *lactobacilli* can directly facilitate or improve the absorption of minerals, particularly calcium, by intestinal cells. It is hypothesized that this desirable effect of *lactobacilli* on the absorption of minerals is linked to the induction of acidification of the microenvironment around the intestinal cells and the bacteria in contact with the intestinal cells. Both the bacteria and the intestinal cells may participate in the induction of acidification. This localized acidification might thus play an active role in the solubilization of minerals and therefore in the capacity of the body to assimilate them. See, Specification, page 2, lines 18-26.

In contrast, neither of the cited references discloses each and every feature of the claimed invention. For example, neither reference discloses that the enteral administration of a nutritional composition including *lactobacilli* can facilitate or improve absorption of minerals, such as calcium and magnesium by intestinal cells, as required by the claimed invention. The *`664* patent merely discloses a culture of a strain of lactic acid bacterium, including three strains of the genus *Bifodobacterium*, that are selected for their affinity for implantation in an intestinal flora. See, *`664*, column 1, lines 64-67. Further, the *`664* patent discloses additional effects of the use of these

strains, particularly as an anti-diarrhoeic. Not one of the additional effects teaches that the strains can facilitate the absorption of minerals by intestinal cells. See, *`664*, column 1, lines 36-42.

Further, the *`302* patent merely discloses a single-specific *Lactobacillus* strain that proves to be capable of competitively displacing pathogenic bacteria, in particular *Helicobacteri pylori*, from intestinal cells. Thus, the *`302* patent, like the *`664* patent, fails to teach that *lactobacilli* can facilitate or improve the absorption of minerals by a mammal, such as by intestinal cells, as required by the claimed invention.

Based on the apparent differences between either of the cited references and the claimed invention, Applicants submit that the references fail to anticipate the claimed invention as required by newly added Claims 11-23.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) be withdrawn.

In the Office Action, Claims 1-10 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over *Yaeshima* and *Yoshida*. The Patent Office essentially asserts that the combined teachings of these references discloses or suggests each and every feature of the claimed invention.

Applicants respectfully submit that this rejection is improper. At the outset, Claims 1-10 have been cancelled and therefore render the rejection thereof moot. As previously discussed, Claims 11-23 have been newly added.

Independent Claims 11, 19 and 23 each relate to methods that comprise the steps of enterally administering to a mammal a nutritional composition comprising *lactobacilli*. Claim 11 further recites a method for treatment or prophylaxis of mineral deficiencies in a mammal. Claim 19 further

recites a method for increasing absorption of minerals from a diet. Claim 23 further recites a method for improving the absorption of minerals in a mammal.

As previously discussed, Applicants have surprisingly found and demonstrated that *lactobacilli* are able to directly facilitate or improve the absorption of minerals, particularly calcium, by intestinal cells. The enhanced mineral absorption effects of *Lactobacillus* have been found not to be linked to the presence of prebiotic fiber; not to be linked to the ability of the cell to adhere to intestinal cells; and not to be linked to the ability of the bacteria to acidify the medium.

As hypothesized, the tested strains of *Lactobacillus* can acidify the microenvironment even if they do not acidify the medium.

In contrast, nowhere do the cited references, alone or in combination, teach or suggest each and every feature of the claimed invention. For example, nowhere does either of the references teach or suggest that the enteral administration of a nutritional composition comprising *lactobacilli* can facilitate or improve the absorption of minerals by a mammal, such as by intestinal cells, as required by the claimed invention.

For example, the *Yoshida* abstract fails to make any reference to *Lactobacillus*, let alone its desirable effects on the absorption of minerals. Moreover, it further suggests that the absorption of calcium is least affected. This teaching is completely opposite of what the Applicants have demonstrated. As seen, for example, in Figure 2 of the Specification, Applicants have shown a particularly pronounced absorption of calcium due to *Lactobacillus*. Further, nowhere does *Yoshida* teach or suggest that the intestinal bacteria increases the absorption of minerals. In this regard, the *Yoshida* Abstract merely discloses that the gnotobiotic mice suffered no deleterious effect on the apparent absorption ratio of total calcium, phosphorus and magnesium. Thus, *Yoshida* clearly fails to teach or suggest each and every feature of the claimed invention.

With respect to *Yaeshima*, at most, this reference appears to disclose that *Bifidobacteria* and not *lactobacterium* can enhance mineral absorption. See, *Yaeshima*, Abstract. The only reference that *Yaeshima* makes to *lactobacilli* is in Figure 1. In this regard, *Yaeshima* merely recognizes that *lactobacilli* can prevent colonization of pathogens and have an effect on the stimulation of immune response. Thus, nowhere does *Yaeshima* make a correlation between *lactobacilli* and enhancing absorption of minerals as required by the claimed invention. In any event, *Yaeshima* clearly does not support the Patent Office's assertion that *lactobacterium* and *Bifidobacterium* are likely to be a substitution of equivalents.

Further, the clear emphasis of *Yaeshima* appears to be that the enhanced effect of mineral absorption is due to the combination of a prebiotic fiber (oligosaccharide) and *Bifidobacterium* as indicated in section 8 of this reference. In contrast, Applicants have demonstrated a direct effect of strains of *Lactobacillus* without the presence of prebiotic fiber or oligosaccharides on the efficacy or activity of cells of the intestinal tract to absorb minerals. Moreover, *Yaeshima* stresses that "some of the effects seem to be general to the genus, and other effects seems to be strain-specific or host-specific." Thus, *Yaeshima* clearly fails to teach or suggest the claimed invention and further fails to provide support for the substitution of *Bifidobacterium* with *lactobacterium*.

Even if combinable, the references fail to remedy the deficiencies of one another. Therefore, based on the apparent differences between the cited references and the claimed invention, Applicants submit that the cited references, alone or in combination, fail to anticipate and/or render obvious the claimed invention as required by Claims 11-23.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the above-identified patent

application is now in a condition for an allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

Robert M. Barrett (Reg. No. 30,142)
BELL, BOYD & LLOYD LLC
P.O. Box 1135
Chicago, Illinois 60690-1135
(312) 807-4204
ATTORNEY FOR APPLICANTS

385168v1/D